

May 1, 2020

Brett Giroir, M.D.
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Stephen Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Assistant Secretary Giroir and Commissioner Hahn,

As the communities we represent consider adjusting mitigation strategies related to COVID-19, it is essential that policy makers, practitioners, and individual citizens have ready access to accurate tests to make informed decisions about how to prevent the virus's spread. Serology tests, which detect the presence of antibodies to COVID-19, can inform physicians about individuals' exposure to COVID-19 and their immune systems' response to it. Serology tests have significant epidemiological value in that they permit us to understand the scope of the epidemic.

Unfortunately, the lack of a consistent strategy and weak oversight of the serology testing market has allowed misinformation to spread and caused a great deal of confusion in the public about the validity and uses of serology tests. Serology tests cannot be used to diagnose COVID-19, since antibodies may supervene infection by several weeks. We also do not know if the presence of antibodies confers immunity to reinfection by COVID-19. And finally, there is the risk of false positives, which could encourage individuals to ease social distancing precautions while they are still vulnerable to infection. Yet, misinformation on all these points continues to plague Americans, including many local policymakers, business owners, or caregivers responsible for making decisions about the safety of others.

On March 16th the Food and Drug Administration (FDA) issued a policy for COVID-19 testing during the public health emergency that outlines the processes for laboratories and manufacturers to bring their tests to market. Section IV.D of that policy allows labs and manufacturers to validate their own serology tests and begin marketing them without applying for an Emergency Use Authorization beforehand. Labs and manufacturers only have to send FDA an e-mail notification before beginning distribution. According to FDA's website, more than 100 labs and manufacturers have brought these serology tests to market under this guidance, but only eight of them have so far received an Emergency Use Authorization.¹

We appreciate the difficulty regulators face in balancing the benefits of allowing expeditious market access and the risks of foregoing important validation tests, especially in an urgent situation like the current public health emergency. Unfortunately, the balance represented by Section IV.D is allowing an unacceptable number of invalidated tests onto the marketplace, leading to further public mistrust and confusion. To correct this issue, we urge FDA and the National Testing Taskforce to undertake the following actions:

¹ "Emergency Use Authorizations," FDA Website, <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.

Conduct a rigorous evaluation of serology tests already on the market. Media reports and stakeholders' reactions suggest that many of these unauthorized serology tests on the market are inaccurate and/or shoddy. Commissioner Hahn seemed to concur with the critics when he warned consumers to be very cautious about tests not backed by an FDA Emergency Use Authorization.²

We are pleased that the Department of Health and Human Services (HHS) has convened an interagency working group to begin the hard work of validating these tests. The Paycheck Protection Program and Health Care Enhancement Act provides \$306 million for the National Cancer Institute to support this effort. We stand ready to offer more support, if necessary, to address this issue.

In the meantime, FDA should take immediate action to assure the validity of serology tests current on the market by:

- Making it more expeditious for serology test developers to apply for an Emergency Use Authorization,
- Clarifying where serology tests can be performed and who is qualified to perform such tests, and
- Monitoring the tests' accuracy post-marketing through extensive data collection.

Begin a public education campaign about the uses and limitations of serology tests. We have heard from constituents, stakeholders, and health professionals in our districts that there is much confusion and a general lack of clarity about the uses and limitations of serology tests.

Unfortunately, the aggressive marketing tactics many labs and manufacturers have exacerbated this widespread confusion. A recent investigation by the House Oversight Committee's Subcommittee on Economic and Consumer Policy identified labs that were mislabeling their tests and making dangerous unfounded public health claims about the tests' utility. One manufacturer said a positive serology test would allow individuals to discontinue social distancing. Other labs have offered their tests for sale directly to consumers for use in their own homes, a violation of Section IV.D's restriction of these tests to providers' offices.³

FDA should take immediate action to address the confusion and misinformation in the marketplace by:

- Requesting and reviewing marketing materials of all serology tests that have not received Emergency Use Authorizations and taking enforcement actions when those marketing materials do not comply with the labeling requirements in Section IV.D,

² The Washington Post, "Confronting COVID-19: FDA Commissioner Dr. Stephen Hahn," April 16, 2020, https://www.washingtonpost.com/video/postlive/confronting-covid-19-fda-commissioner-dr-stephen-hahn/2020/04/16/9ce3d150-fe00-44a4-892a-a310fba2f4e_video.html?itid=lk_inline_manual_9.

³ Memorandum from the Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy Staff, April 24, 2020, <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Staff%20Report%20on%20Preliminary%20Findings%20of%20the%20Subcommittee%E2%80%99s%20Coronavirus%20Antibody%20Testing%20Investigation.pdf>

- Working with the Centers for Disease Control and Prevention and the National Testing Taskforce to educate the public about the uses and limitations of serology tests, and
- Moving forward, requesting copies of labs' and manufacturers' marketing materials as part of any marketing notification so as to be able to take proactive action if necessary.

Comply with the legal requirements to design and implement a national testing strategy, including recommendations related to the use of serology tests. Finally, we write to express our concern about the overall lack of a national strategy to increase access to testing and ability to aggregate and interpret those results in real time.

We found the "Blueprint for Testing Plans and Reopening America" which the Administration put forward earlier this week to be lacking many crucial details. The document does not set numeric goals, establish a timeframe, or offer details on expanding lab capacity. We are especially concerned that the Administration is continuing with its "you're on your own" message to the states, which has created a chaotic and confusing marketplace for personal protective equipment, testing reagents and swabs, and other necessary materials for the fight against COVID-19.

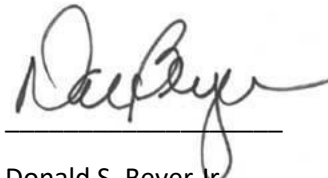
We are disappointed that it took Congressional action to force the Administration's hand in this area. We look forward to HHS's compliance with the Paycheck Protection Program and Health Care Enhancement Act requirement that the agency submit a strategic COVID-19 testing plan to Congress. We expect that plan to include a strategy for deploying serology tests in a way that is consistent with the scientific value of these tests and the public health interests they can serve.

Thank you for your attention to these matters. We look forward to working with you to improve America's response to the COVID-19 public health emergency.

Sincerely,



Abigail D. Spanberger
Member of Congress



Donald S. Beyer Jr.
Member of Congress